REMARKS

Claims 25-40 are active in the present application.

The rejection of Claims 25-30 under 35 U.S.C. §103(a) over Takahara et al in view of Gibbons is traversed.

Takahara et al disclose a process for producing a molecule for binding a nucleic acid, which molecule comprises a biologically active peptide or protein bound to a high molecular weight substance that is capable of binding a nucleic acid (see Abstract). Takahara et al further disclose that the conjugate so formed is useful for carrying out gene transfer therapy (page 2, lines 1-2).

Gibbons discloses an agglutination assay using a reaction medium containing, a sample, a plurality of particles having a binding pair member bound to the surface, and a monovalent complementary partner to the binding pair member to which an analyte mimic or analyte binding partner is attached (column 2, lines 15-24).

The Examiner asserts that Takahara et al provide motivation for using an "antigen comprising a nucleic acid bound antibodies," and as such, it would be obvious to use these products in the agglutination immunoassay of Gibbons (paper number 14, page 6, lines 11-13). However, Takahara et al do not disclose or suggest forming an antigen produced by binding a nucleic acid to a polypeptide followed by fixing the nucleic acid-bound polypeptide on the surface of a particle, as claimed in the present application (see Claim 25). Nor do Takahara et al suggest that such an antigen would be suitable for an agglutination immunoassay. In the absence of such a disclosure or suggestion, there would be no motivation to combine the disclosure of Takahara et al with Gibbons to arrive at the present invention.

Takahara et al define biologically-active peptides or proteins as being "peptides which exhibit a physiological action in the human body. . . ; peptides obtained by modifying the above-mentioned peptides; substances derived from animals. . . ; substances derived from plants. . . Antibodies" etc. (page 2, lines 5-14). One of skill in the art would not select an antibody from the extensive list of suitable biologically-active peptides or proteins as alleged by the Examiner. Moreover, Takahara et al disclose that the preferred high molecular weight substance that binds to the DNA is polylysine (page 4, lines 35-36), which is clearly not an antibody. Accordingly, the assertion that Takahara et al would motivate the skilled artisan to practice the claimed invention can not reasonably be maintained.

As indicated by the Examiner, Gibbons discloses that the binding pairs envisioned by their invention include antigens and antibodies or complementary nucleic acid strands (paper 14, page 6, lines 13-14). However, at no point does Gibbons suggest that the antigen is a nucleic acid-bound polypeptide affixed to the surface of a particle. Accordingly, the Examiner has merely cited Gibbons for its utility as an immunoassay despite the absence of a nexus between Takahara et al and Gibbons.

In fact, but for the disclosure of the present application, the skilled artisan would be concerned about an adverse affect on antigenicity arising from the occlusion of the epitope for antibody binding caused by direct DNA binding and/or a conformational change in the target protein due to DNA binding. As shown in Table 2 of the specification at page 29 (reproduced below for the Examiner's convenience), the Applicants have compared the immune reactivity of HCV antigen-fixed gelatin particles in the absence of DNA (120NA, 120K10, and 120) and the presence of DNA (120NA(+)):

TABLE 2

Immune Reactivity Tests of HCV Core Antigens

Name of Core Antigen	Positive Serum 1	Positive Serum 2	#2-7
120NA(+)	6+	7	8
120NA	<3	<3	7
120K10	<3	<3	6
120	<3	<3	4

An immune reactivity was judged as "positive" when "n" is greater than 4 based on a dilution rate of 2^n (page 28, lines 15-18). A positive immune reactivity for HCV-positive serum 1 and 2 could only be detected when the HCV antigen-fixed gelatin particles were in the presence of DNA (6+ and 7 for 120 NA(+), respectively). Therefore, the antigenic properties of the polypeptide to the antibody were increased by binding the polypeptide to a nucleic acid. This increase in assay sensitivity was not expected in view of Takahara et al and Gibbons.

Hence, this ground of rejection is unsustainable and should be withdrawn.

The Examiner further cites Ono et al in combination with Takahara et al and Gibbons in rejecting Claims 31 and 32 under 35 U.S.C. §103. Ono et al disclose the amino acid sequence shown in SEQ ID NO:2; however, it does not overcome the deficiencies in the combined disclosures of Takahara et al and Gibbons.

Accordingly, this ground of rejection is also unsustainable and should be withdrawn.

The rejections under 35 U.S.C. §112, second paragraph are obviated by amendment. Further, the rejections under 35 U.S.C. §103(a) of Claims 17-22 over Takahara et al in view of Weiner et al and of Claims 23-24 Takahara et al in view of Weiner et al and of Ono et al are obviated by the cancellation of Claims 17-24.

Applicants submit that the present application is now in condition for allowance.

Early notification of such action is earnestly solicited.

Respectfully submitted,

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Marked-Up Copy
Serial No: 09/306,780
Amendment Filed on:
Herewith

IN THE SPECIFICATION

Page 1, after the title and preceding the Background of the Invention, beginning on a new line, please insert following:

Cross-reference to Related Applications

This application is a Divisional Application of U.S. Application Serial No. 08/841,657 filed April 30, 1997 (now abandoned), which claims priority to Japanese Patent Application No. 8-134444 filed May 1, 1996.

IN THE CLAIMS

Claims 17-24 (Cancelled).

Please amend the claims as shown on the marked-up copy attached to read as follows:

25. (Amended) An agglutination immunoassay for assaying an antigen, comprising an antigen and either a polypeptide[,] or an antibody corresponding to said antigen, or both, wherein [using as] said antigen is a nucleic acid-bound polypeptide which is produced by:

(A) binding a nucleic acid to a polypeptide[, and];

(B) fixing said nucleic acid-bound polypeptide on the surface of [particles] a particle; and

wherein said immunoassay further comprises:

(i) contacting said antigen with said antibody; and

(ii) detecting the resultant antigen-antibody complex.

31. (Twice Amended) The agglutination immunoassay [as claimed in] according to Claim 27, wherein said nucleic acid-binding motif has an amino acid sequence [with] as set forth in SEQ ID NO:2.

32. (Twice Amended) The agglutination immunoassay [as claimed in] according to Claim 28, wherein said nucleic acid-binding motif has an amino acid sequence [with] as set forth in SEQ ID NO:2.

Claims 33-40 (New).